

REMARKS

Status of Claims

Claims 37-41, 57, and 73 are pending. Claim 37 is the only independent claim. Claims 38 and 40-41 are presently withdrawn. In this Reply, without conceding the propriety of the rejection and in order to expedite prosecution, independent claim 37 has been amended. Dependent claims 38-41 and 57 have been amended and claims 48, 50-51, and 54-56 have been canceled to conform with the amendments to claim 37. Support for the amendments exists, *inter alia*, in the original claims and at paragraph [0010] of the specification. No new matter has been added. Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to subject matter deleted from the claims.

Applicants respectfully request the Examiner to reconsider and withdraw the rejections in view of the foregoing amendments and the following remarks.

Claim Rejection Under 35 U.S.C. § 103

The rejection of claims 37, 39, 48, 50-51, 54-57, and 73 under 35 U.S.C. § 103(a) over Chutka et al., "Urinary Incontinence in the Elderly: Drug Treatment Options," 1998, Drugs, Volume 56, Number 4, pages 587-595 ("Chutka et al.") in view of U.S. Patent No. 6,248,737 ("Buschmann et al. '737") and Andersson et al., "The pharmacological treatment of urinary incontinence," 1999, British Journal of Urology International, 84:923-947 ("Andersson et al.") is respectfully traversed.

The presently claimed composition of matter of independent claim 37 comprises as an admixture (+)-(2R,3R)-1-dimethylamino-3-(3-methoxy-phenyl)-2-methyl-pentan-3-ol or a salt thereof with a physiologically tolerated acid and oxybutynin or a salt thereof with a physiologically tolerated acid. (+)-(2R,3R)-1-dimethylamino-3-(3-methoxy-phenyl)-2-methyl-pentan-3-ol or a salt thereof with a physiologically tolerated acid and oxybutynin or a salt thereof with a physiologically tolerated acid are present at dosages that provide a synergistic

effect for the treatment of urinary incontinence.

One of ordinary skill in the art can easily determine the recited dosages that provide a synergistic effect for the treatment of urinary incontinence by routine experimentation.

The synergistic effect of the presently claimed composition of matter for the treatment of urinary incontinence is unexpected and demonstrated in Example 1 of the specification. The synergistic effect demonstrated in Example 1 is commensurate with the scope of the claims.

Example 1 tested (+)-(2*R*,3*R*)-1-dimethylamino-3-(3-methoxy-phenyl)-2-methyl-pentan-3-ol hydrochloride in combination with oxybutynin. In Example 1, individual administration of the tested compound to rats provided 21.7% inhibition of the rate of bladder contractions and individual administration of oxybutynin provided 10.7% inhibition of the rate of bladder contractions. In contrast, administration of the combination of the tested compound and oxybutynin provided 42.5% inhibition of the rate of bladder contractions. Thus, combined administration of the tested compound and oxybutynin provides a synergistic (i.e. supra-additive) effect.

The unexpected, synergistic effect of the presently claimed composition of matter effectively rebuts any *prima facie* case of obviousness over Chutka et al., Buschmann et al. '737, and Andersson et al.

Therefore, for at least the reasons discussed above, withdrawal of the § 103(a) rejection over Chutka et al., Buschmann et al. '737, and Andersson et al. is respectfully requested.

Conclusion

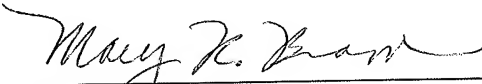
In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

If there are any questions relating to this Reply or the application in general, it would be appreciated if the Examiner could telephone the undersigned at (202) 624-2845 so that examination of this application may be expedited.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 029310.53299US).

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